

REMARKS

In the outstanding Final Office Action of September 19, 2007, claims 1-4, 6-16, and 19-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon, U.S. Patent No. 5,879,336, in view of Kulle, U.S. Patent No. 4,346,704; claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Kulle and further in view of Riuli, U.S. Pat. No. 4,713,060; and claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Riuli and further in view of Kulle. Applicant traverses these rejections for the reasons set forth below.

A. Rejections Under § 103(a) over Brinon in view of Kulle

1. Claims 1-4, 6-10, 13, and 19-22

Claim 1 recites a sterile sheath for an injection syringe comprising "a sealed casing made of plastic, the casing including an output connection piece, wherein the output connection piece includes a valve whose direction of flow is exclusively from an injection syringe to the exterior . . . wherein the output connection piece is configured to be connected to the syringe, wherein the output connection piece includes at least one radial discharge aperture sealable by means of an elastic ring element." Claims 2-4, 6-10, 13, and 19-22 depend from independent claim 1.

With respect to independent claim 1 and dependent claims 2-4, 6-10, 13, and 19-22, the Office Action asserts that Brinon discloses the invention substantially as claimed except for at least one radial discharge aperture sealable by means of an elastic ring element. Office Action, pp. 2-4. The Office Action relies on Kulle for allegedly teaching use of a radial discharge aperture sealable by means of an elastic ring element, and argues that it would have been obvious to modify the valve of Brinon with the radial

discharge aperture of Kulle “for the purpose of providing a one-way valve with low residual volume so that critical medications may be administered in precise quantities with less waste while also providing higher flow rates at lower pressures.” Office Action, p. 4.

Applicant respectfully disagrees. The Office Action relies upon Brinon as the base reference and suggests modifying that reference with Kulle. Applicant submits that modification as taught by Kulle renders Brinon unsuitable for its intended purpose, and as such, a *prima facie* case of obviousness has not been established. See M.P.E.P. § 2143.01, subsection V. The purpose of the device of Brinon is to enable delivery of successive doses of a liquid while ensuring that the time period between two successive administrations cannot be less than a reference value (col. 1, ll. 4-7). Brinon teaches that controlled suction ensures a proper time period between administrations (col. 3, ll. 54-60). Brinon also teaches that a non-return valve, especially a “duck bill” type non-return valve, ensures proper suction (col. 3, ll. 54-56; col. 2, ll. 14-28).

The Office Action argues that it would be obvious to replace the non-return valve of Brinon with the unidirectional valve as taught by Kulle. However, replacing the valve of Brinon with that of Kulle would substantially destroy the invention of Brinon because the benefits Brinon teaches specifically depend on a valve suited to withstand substantial upstream negative pressures. According to Brinon, the piston returns almost at once to its initial position, thus subjecting the chamber to suction (col. 3, ll. 51-60). Kulle discloses a valve tube that freely floats around an aperture (col. 2, ll. 56-58) and has a rear end that is free to open and contribute additional flow (col. 2, ll. 66-68).

Both the free-floating and open-rear-ended nature of the Kulle valve weaken its abilities to withstand substantial upstream negative pressures, making it unsuitable for use with Brinon. Because the proposed modification would render the device of Brinon unsatisfactory for its intended purpose, there is no suggestion to make the modification proposed by the Examiner. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). See also M.P.E.P. § 2143.01. Accordingly, the instant claims are not unpatentable over the combination.

Applicant further submits that Brinon teaches away from combination with Kulle. M.P.E.P. § 2145, subsection X.D.2. The combination of Brinon with Kulle would not be obvious to one of ordinary skill in the art, because Brinon specifically teaches away from combination with such technologies. One of ordinary skill in the art thus would have no motivation to make such a combination. Brinon teaches that the “device does not include any external tube that could constitute the cause of an accident, other than the tube connected to its injection outlet” (col. 1, ll. 43-45). Kulle discloses a sleeve valve for parenteral solution device, which includes *two* external tubes. As taught in Kulle, at one end of the valve housing is a substantial length of tubing (col. 1, ll. 14-15), and at the other end of the valve housing is a luer for receiving a syringe for medication (col. 1, ll. 23-26). The “substantial length of tubing” of Kulle is precisely the type of “external tube that could constitute the cause of an accident” disparaged in Brinon. Because there is no motivation to combine Kulle with Brinon, the alleged combination does not render the instant claims obvious.

For at least the above reasons, neither Brinon nor Kulle, either alone or in combination, render claim 1 and dependent claims 2-4, 6-10, 13, and 19-22 unpatentable.

2. Claim 7 Additional Features

In addition to the features of claim 1, claim 7 further requires that “the output connection piece includes a cone-shaped recess configured to receive a syringe cone of the injection syringe.” The cone-shaped recess may make the sheath suitable for use with commercially available injection syringes (para. 16).

The Office Action asserts that the same combination of Brinon and Kulle applied to claim 1 also discloses the features of claim 7. Applicant respectfully disagrees. Neither Brinon nor Kulle discloses at least the “cone-shaped recess” of dependent claim 7. Brinon teaches a cylindrical case containing a piston that includes a cartridge. Kulle teaches an output port, which may seal the an end of tubing. Furthermore, although Kulle teaches a rear end that may be configured to receive the tapered end of a syringe (col. 4, ll. 7-11), the rear end is not part of the “output piece.” Nothing in Brinon, alone or in combination with Kulle, teaches or suggests an “output connection piece [that] includes a cone-shaped recess configured to receive a syringe cone of the injection syringe.” Further, the design of Brinon, including pushbutton 18 and returnable piston 3, would make use of commercially available syringes infeasible, and thus eliminates motivation for such a modification.

For at least the above reasons, neither Brinon nor Kulle, either alone or in combination, render dependent claim 7 unpatentable.

3. Claim 10 Additional Features

In addition to the features of claim 1, claim 10 requires that “the output connection piece includes, on an end opposite from the valve, an annular plate.” The Office Action asserts that the same combination of Brinon and Kulle applied to claim 1 also discloses the features of claim 10.

Applicant respectfully disagrees. Claim 10 is not unpatentable for at least the reasons that claim 1 is not unpatentable. Additionally, neither Brinon nor Kulle discloses at least that “the output connection piece includes, on an end opposite from the valve, an annular plate,” as required by dependent claim 10. Brinon teaches a cylindrical case having passages formed on its side, with the passages accepting arms of a cover such that the cover cannot be removed without breaking the arms. Kulle teaches a sleeve valve having a tubular support that is free of tubular retaining structure, and a rear end shaped to receive a syringe. Neither of these structures suggest the claimed structure.

For at least the above reasons, neither Brinon nor Kulle, either alone or in combination, renders dependent claim 10 unpatentable.

4. Claim 13 Additional Features

In addition to the features of claim 1, claim 13 recites that “the sealable casing further comprises a pressure pocket configured to connect to the output connection piece.” With respect to dependent claim 13, the Office Action asserts that the same combination of Brinon and Kulle as applied to claim 1 also discloses the features of claim 13.

Applicant respectfully disagrees. Neither Brinon nor Kulle discloses or suggests at least “a pressure pocket configured to connect to the output connection piece” as required by dependent claim 13. Brinon teaches a cover mounted at the top of the case, with the cover including an opening allowing access to a push button. Kulle teaches a valve housing with a port that may seal to tubing and a rear end shaped to receive a syringe. Neither of these structures suggest the claimed structure.

For at least this additional reason, claim 13 is patentable over Brinon and Kulle, both alone and in combination.

5. Claim 11 Additional Features

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Kulle.

In addition to the features of claim 10, claim 11 further requires that “the annular plate has an oval aperture.”

The Office Action asserts that Brinon in view of Kulle discloses the invention substantially as claimed, and that it would have been an obvious matter of design choice to modify the combination to obtain the features of claim 11. Office Action, pp. 4-5. Specifically, the Office Action asserts that “Applicant has not disclosed that having an annular plate with an oval aperture provides an advantage, is used for a particular purpose, or solves a stated problem.” Office Action, p. 5.

Applicant respectfully disagrees. Claim 11, depending from claim 10, is patentable over Brinon in view of Kulle at least for the above reasons that claims 1 and 10 are patentable. Further, Applicant submits that an oval aperture would not be an obvious matter of design choice, because there is no motivation to combine Brinon and

Kulle as suggested by the Examiner. Additionally, Applicant respectfully disagrees with the Office Action's characterization that Applicant has not disclosed the advantages, purpose, or solutions posed by the oval aperture. The specification states that "[b]ecause of the configuration of the injection syringe, with handle ribs which extend perpendicularly to the direction in which the syringe plunger is displaced, it is considered to be advantageous if the output connection piece exhibits an oval ring aperture" (para. 22). Furthermore, Brinon teaches a cylindrical case containing a piston that includes a cartridge. The pushbutton 18 and returnable piston 3 design of Brinon make the use of commercially available syringes infeasible, and thus such a modification is undesirable. For this reason, one of ordinary skill in the art would not be motivated to provide Brinon's device with "an annular plate [having] an annular aperture."

For at least the above reasons, neither Brinon nor Kulle, either alone or in combination, render dependent claim 11 unpatentable.

6. Claim 12

Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Kulle. Claim 12 depends from claim 1 and is thus patentable over Brinon and Kulle for at least the same reasons discussed above with regard to claim 1.

7. Claims 14-16

Claims 14-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Kulle. Claims 14-16 depend from claim 13 and are thus patentable over Brinon and Kulle for at least the same reasons discussed above with regard to claims 1 and 13.

B. Rejections under § 103(a) over Brinon in view of Kulle in further view of Riuli

Claims 17-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Kulle in further view of Riuli, U.S. Pat. No. 4,713,060.

In addition to the features of claim 13, dependent claim 17 further requires “a shoulder piece configured to connect to the output connection piece, and further includes a film-like plastic hood.” Claim 18, depending from claim 17, further requires that “the shoulder piece includes a snap-in lug configured to engage a snap-in lug on an annular plate of the output connection piece.”

The Office Action asserts that Brinon in view of Kulle discloses the invention as claimed except for where the pressure pocket includes a shoulder film-like plastic hood. Office Action, p. 6. The Office Action alleges that Riuli teaches to use “a shoulder film-like plastic hood for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow the transfer of fluid and particulate matter between the chamber and the environment.” Office Action, p. 6. The Office Action asserts that it would be obvious to modify the combination to use a “flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow [sic] the transfer of fluid and particulate matter between the chamber and the environment.” Office Action, p. 6.

Applicant respectfully disagrees. Claims 17-18, depending from claims 1 and 13, are not unpatentable over Brinon in view of Kulle in further view of Riuli at least for the above reasons that claims 1 and 13 are not unpatentable over Brinon and Kulle. Additionally, Applicant respectfully disagrees with the Office Action using Brinon with Riuli as a base reference and suggesting modification with Kulle.

Applicant submits that modification as taught by Riuli would render Brinon unsuitable for its intended purpose, and as such, a *prima facie* case of obviousness has not been established. See M.P.E.P. § 2143.01, subsection V. The purpose of the device of Brinon is to enable deliver of successive doses of a liquid while ensuring that the time period between two successive administrations cannot be less than a reference value (col. 1, ll. 4-7). Brinon teaches that “pushbutton 18 is pierced to admit air into the reservoir above the moving plug so that atmospheric pressure acts on the moving plug” (col. 3, ll. 21-23). Using the cover of Riuli would substantially destroy the invention of Brinon, because Brinon’s benefits specifically depend on allowing atmospheric pressure to act on the moving plug (col. 3, ll. 21-23). Riuli discloses a cover that “acts as a barrier for helping to block the transfer of fluid and particulate matter between the chamber and the environment” (abstract). Such a cover is unsuitable for use with Brinon because it could hinder movement of the plug 17. Because the proposed modification would render the device of Brinon unsatisfactory for its intended purpose, there is no suggestion to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). See also M.P.E.P. § 2143.01.

Applicant also submits that the alleged combination of Brinon in view of Kulle in further view of Riuli does not teach all of the features of claim 18. Claim 18 requires a “snap-in lug configured to engage a snap-in lug on an annular plate of the output connection piece.” Because claim 18 requires an “annular plate,” the asserted combination does not render claim 18 unpatentable for the same reasons that Brinon and view of Kulle do not render claim 10 unpatentable.

C. Rejection under § 103(a) over Brinon in view of Riuli in further view of Kulle

Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinon in view of Riuli in further view of Kulle.

In addition to the features of claim 1, dependent claim 23 further requires “a pressure pocket configured to connect to the output connection piece, wherein the output connection piece further includes at least one radial discharge aperture sealable by means of an elastic ring element; a cone-shaped recess configured to receive a syringe cone of the injection syringe; and an annular plate, on an end of the output connection piece opposite the valve, configured to connect to the pressure pocket.”

The Office Action asserts that Brinon in view of Riuli discloses the invention as claimed, “except for wherein the output connection piece further includes at least one radial discharge aperture sealable by means of an elastic ring element.” Office Action, p. 7. According to the Office Action, Kulle allegedly teaches “at least one radial discharge aperture sealable by means of an elastic ring element for the purpose of providing uni-directional flow with a low residual valve size.” Office Action, p. 7. The Office Action asserts that it would be obvious to replace the valve as taught by Brinon in view of Riuli with the valve as taught by Kulle for the purpose of providing uni-directional flow with a low residual valve size. Office Action, p. 7.

Applicant respectfully disagrees. Claim 23, depending from claim 1, is not unpatentable over Brinon in view of Riuli in further view of Kulle at least for (1) the above reasons that claim 1 is not unpatentable over Brinon and Kulle and (2) the above reasons that claims 17-18 are not unpatentable over Brinon, Kulle, and Riuli. Specifically, the proposed modifications render the device of Brinon unsatisfactory for its

intended purpose; therefore, there is no suggestion to make the proposed modification.

In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). See also M.P.E.P.

§ 2143.01. Additionally, claim 23 requires "an annular plate," which is not taught or suggested by the proposed combination of Brinon, Kulle, and Riuli.

In view of the foregoing remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the Examiner's reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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